

## **REMARKS**

### **I. Background**

The present Amendment is in response to the Office Action mailed June 25, 2007. Claims 1-42 were pending in the application for consideration at the time of the mailing of the Office Action. Claims 1, 2, 4, 9, 10, 21, and 33 are currently amended.<sup>1</sup> Thus, claims 1-42 remain pending for consideration on the merits.<sup>2</sup>

### **II. Rejection on the Merits**

#### **A. Rejections Under 35 U.S.C. § 103(a)**

The Office Action rejects claims 1-9 under 35 U.S.C. § 103(a) as being unpatentable over *Goosen et al.* (U.S. 4,942,129) in view of *Struszczyk et al.* (U.S. 5,554,445). Applicant respectfully traverses the rejection because the combination of *Goosen* and *Struszczyk* does not teach or suggest each and every element of the presently pending claims as amended, and thereby a *prima facie* case of obviousness has not been established.

According to Applicant's understanding, *Goosen* teaches that alginate gels can include chitosan as an optional minor component. In fact, *Goosen* only teaches the use of chitosan in lieu of or in addition to PLL (Col. 3, lines 37-65; col. 4, lines 25-28). *Goosen* teaches that the chitosan is produced by a reaction of sodium nitrate with the chitosan being at a "concentration of 0.01-0.03% (w/v)" (Col. 3, lines 57-62). *Goosen* teaches that the "[c]hitosan-alginate microcapsules were prepared by replacing the PLL solution with 30 mL of 0.1% (w/v) chitosan derivative" (col. 11, lines 40). Examples 1-3 of *Goosen* teach the use of PLL in forming alginate gels. Since the gels of *Goosen* are taught to be alginate gels, *Goosen* is completely devoid of teaching or suggesting a gel agent consisting essentially of chitosan or a chitosan salt.

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1 The amendments to claims 1, 4, 9, 10, 21, and 33 are fully supported by the specification and examples provided in the patent application as filed. Thus, Applicant respectfully submits that the amendments to the claims do not introduce new matter and entry thereof is respectfully requested.

2 Reconsideration of the application is respectfully requested in view of the above amendments to the claims and the following remarks. For the Examiner's convenience and reference, Applicant's remarks are presented in the order in which the corresponding issues were raised in the Office Action. Please note that the following remarks are not intended to be an exhaustive enumeration of the distinctions between any cited references and the claimed invention. Rather, the distinctions identified and discussed below are presented solely by way of example to illustrate some of the differences between the claimed invention and the cited references. In addition, Applicant requests that the Examiner carefully review any references discussed below to ensure that Applicant's understanding and discussion of the references, if any, is consistent with the Examiner's understanding.

According to Applicant's understanding, *Struszczyk* teaches microcrystalline chitosan films that are applied to seeds for preservation (Abstract). However, *Struszczyk* is completely devoid of teaching or suggesting a chitosan gel. Thus, *Struszczyk* is completely devoid of teaching or suggesting a gel agent consisting essentially of chitosan or a chitosan salt. Furthermore, *Struszczyk* is completely devoid of teaching or suggesting a chitosan-calcium complex consisting essentially of chitosan and calcium.

Applicant respectfully disagrees with the characterization of the meaning of the legally-recognized phrase "consisting essentially of" recited in the Office Action. Contrary to the Office Action, "consisting essentially of" is not merely "an open-ended phrase, which allows for the presence of additional components in the chitosan calcium complex." According to the MPEP<sup>3</sup>, the phrase "consisting essentially of" limits the scope of a claim to the specified materials "and those that do not materially affect the basic and novel characteristics(s)" of the claimed invention.<sup>4</sup> As such, the claimed gel agent of claim 1 "consists essentially of a chitosan salt" and thereby does not include any other gel agent that materially affects the basic and novel characteristics of the claimed invention. The alginate gels of *Goosen* do not "consist essentially of a chitosan salt" because the sodium alginate materially affects the characteristics of the chitosan-containing composition. In fact, the only example<sup>5</sup> in *Goosen* of a gel that includes chitosan as a gel agent teaches that "[c]hitosan-alginate microcapsules were prepared by replacing the PLL solution with 30 mL of 0.1% (w/v) chitosan derivative." As can be seen in Examples 1-3 of *Goosen*, alginate is a major component that materially affects the characteristics of the cell-encapsulating composition of *Goosen*. Therefore, "a gel agent consisting essentially of a chitosan salt" is substantially devoid of having an alginate gel.

In view of the above, Applicant respectfully submits that the combination of *Goosen* and *Struszczyk* does not teach or suggest each and every element of the presently claimed invention of independent claims 1 and 4. More particularly, the combination of *Goosen* and *Struszczyk* is completely devoid of any teaching or suggestion regarding "a chitosan-calcium (II) complex consisting essentially of chitosan and calcium," or "gel agent consisting essentially of a chitosan salt," as recited in claim 1, or "a gel agent consisting essentially of chitosan" or "complex consisting essentially of chitosan and calcium," as recited in claim 4. In part, this is because

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<sup>3</sup> MPEP § 2111.03

<sup>4</sup> *In re Herz*, 537 F.2d 549, 551-52, 190 USPQ 461, 463 (CCPA 1976) (emphasis in original).

<sup>5</sup> Example 7

*Goosen* only teaches that alginate gels may include chitosan, and thereby alginate is a component that would materially affect the basic and novel characteristics of the chitosan-containing composition as claimed in the present application. In another part, *Struszczyk* teaches microcrystalline chitosan films for coating seeds, and is completely devoid of teaching or suggesting a chitosan-containing gel. As such, nothing in the combination of *Goosen* and *Struszczyk* teaches or suggests a gel agent that consists essentially of chitosan or a chitosan salt.

Additionally, Applicant respectfully asserts that there is no motivation, suggestion, or reason to modify the teachings of *Goosen* and/or *Struszczyk*. Nothing in *Struszczyk* provides any motivation, suggestion, or valid reason that the chitosan can be a gel agent consisting essentially of a chitosan or chitosan salt. Also, nothing in *Goosen* provides any motivation, suggestion, or valid reason for the alginate to be removed, or that the alginate does not materially affect the basic and novel characteristics of the chitosan-containing composition.

Even if combined, the combination of *Goosen* and *Struszczyk* does not teach or suggest each and every limitation of independent claims 1 and 4, a *prima facie* case of obviousness has not been established. Claims 2-3 and 5-9 depend from independent claims 1 or 4, and thereby incorporate the limitations thereof. As such, Applicant respectfully submits that claims 2-3 and 5-9 are allowable over the combination of *Goosen* and *Struszczyk* for at least the same reasons as discussed above with regard to claims 1 and 4. Thus, the Applicant respectfully requests reconsideration and withdrawal of the rejections to claims 1-9 under 35 U.S.C. § 103(a), relative to the combination of *Goosen* and *Struszczyk*.

#### **B. Rejections Under 35 U.S.C. § 103(a)**

The Office Action rejects claims 10-42 under 35 U.S.C. § 103(a) as being unpatentable over *Nies et al* (EP 650999 A1) or *Hashimoto et al* (U.S. Patent No. 5,474,989) in view of *Goosen* or *Struszczyk*. Applicant respectfully traverses the rejection because the combination of *Nies* and/or *Hashimoto* and *Goosen* and/or *Struszczyk* does not teach or suggest each and every element of the presently pending claims as amended, and thereby a *prima facie* case of obviousness has not been established.

The foregoing discussions of *Goosen* and/or *Struszczyk* are relevant to the instant rejection and are incorporated into this remark by specific reference. Additionally, Applicant respectfully asserts that the combination of *Nies* and/or *Hashimoto* does not cure the deficiencies

of *Goosen* and/or *Struszczyk* recited above with respect to the rejection of claims 1-9, which are applicable to the rejections of claims 10-42.

According to Applicant's understanding, *Nies* teaches chitosan aqueous solutions or gels are prepared by "dissolving chitosan and an acid chelate complex former (I) in water" to form a solution, and high viscosity gels are obtained by additionally adding to the solution "polyvalent metal/acid salts in which chitosan is only slightly soluble" (e.g., calcium salts) (Abstract). Examples of the acid chelate complex former (I) of *Nies* include "nitrilo-acetic acid, EDTA, diethylenetriamine penta-acetic acid, triethylenetetramine hexa-acetic acid or diaminocyclohexane tetra-acetic acid/abstracts." However, *Nies* is completely devoid of teaching or suggesting a process of degrading chitosan. Additionally, *Nies* is completely devoid of teaching or suggesting adding an aqueous basic solution to a chitosan mixture to attain  $4.0 \leq \text{pH} \leq 6.0$ . Furthermore, *Nies* is completely devoid of teaching or suggesting continuously mixing a chitosan composition with a calcium (II) salt until a gel having a gel agent consisting essentially of a chitosan salt forms, wherein said gel agent contains  $\geq 0.5$  wt % chitosan having an average molecular weight  $\geq 10$  kD, a polydispersity  $\geq 2.0$ , deacetylation degree  $\geq 65\%$  and wherein said complex has a water retention value  $\geq 300\%$ ,  $\text{pH} \leq 6.9$ , and calcium (II) ions bound to the chitosan at a content  $\geq 0.1$  wt % relative to chitosan. Moreover, *Nies* is completely devoid of teaching or suggesting a chitosan-calcium (II) complex consisting essentially of chitosan and calcium.

According to Applicant's understanding, *Hashimoto* only teaches or suggests degradation of chitosan for use in preparing a drug composition (Abstract). However, *Hashimoto* is completely devoid of teaching or suggesting a method for preparing a chitosan gel or chitosan salt gel. Additionally, *Hashimoto* is completely devoid of teaching or suggesting continuously mixing a chitosan composition with a calcium (II) salt until a gel having a gel agent consisting essentially of a chitosan salt forms, wherein said gel agent contains  $\geq 0.5$  wt % chitosan having an average molecular weight  $\geq 10$  kD, a polydispersity  $\geq 2.0$ , deacetylation degree  $\geq 65\%$  and wherein said complex has a water retention value  $\geq 300\%$ ,  $\text{pH} \leq 6.9$ , and calcium (II) ions bound to the chitosan at a content  $\geq 0.1$  wt % relative to chitosan. Moreover, *Hashimoto* is completely devoid of teaching or suggesting a chitosan-calcium (II) complex consisting essentially of chitosan and calcium.

Applicant respectfully asserts that the combination of *Nies* and/or *Hashimoto* and *Goosen* and/or *Struszczyk* does not teach or suggest each and every element of the presently pending

claims 10, 21, and 33. More particularly, nothing in the combination of references teaches or suggests continuously mixing chitosan “with a calcium (II) salt until a gel having a gel agent consisting essentially of a chitosan salt” to obtain a “complex consisting essentially of chitosan and calcium,” as recited in claims 10, 21, and 33. *Nies* does not provide such a teaching or suggestion because the chitosan is combined with an acid chelate complex former (I) in a significant amount that materially affects the basic and novel characteristics of the chitosan-containing composition. Neither *Hashimoto* nor *Struszczyk* provide such a teaching or suggestion because no chitosan gel is taught or suggested in either reference. *Goosen* does not provide such a teaching because the alginate gels may include chitosan, and thereby alginate is a component that materially affects the basic and novel characteristics of the chitosan-containing composition. Further the combination of references fails to teach a complex consisting essentially of chitosan and calcium. Thus, the combination of references does not teach or suggest each and every element of the present invention recited in claims 10, 21, and 33.

Additionally, Applicant respectfully asserts there is no motivation, suggestion, or valid reason to modify the teachings of the combination of *Nies* and/or *Hashimoto* and *Goosen* and/or *Struszczyk* in order to arrive at the present invention. For example, nothing in *Hashimoto* and/or *Struszczyk* references provides any motivation, suggestion, or valid reason that the chitosan composition taught therein can be prepared into a chitosan salt gel having a gel agent consisting essentially of a chitosan salt or a complex consisting essentially of chitosan and calcium by the claimed processes recited in claims 10, 21, and 33. Additionally, nothing in *Nies* provides any motivation, suggestion, or valid reason that the acid chelate complex former (I) can be removed from the gel or does not materially affect the basic and novel characteristics of the chitosan-containing gel. Further, nothing in *Goosen* provides any motivation, suggestion, or reason that the alginate (or other substance described in col. 4, lines 1-17) can be removed from the gel or does not materially affect the basic and novel characteristics of the chitosan-containing gel. Accordingly, the combination of references do not provide any motivation, suggestion, or reason to modify the teachings thereof in order to arrive at a process to produce a chitosan salt gel having a gel agent consisting essentially of a chitosan salt. Further the combination of references fails to provide any valid reason to form a complex consisting essentially of chitosan and calcium. Thus, there is no motivation, suggestion, or valid reason to modify any of the references, alone or in combination, in order to arrive at the present invention recited in claims 10, 21, and 33.

Since the combination of *Nies* and/or *Hashimoto* and *Goosen* and/or *Struszczyk* does not teach or suggest each and every element of the presently claimed invention, and/or provide any motivation, suggestion, or reason to modify the references, alone or in combination, in order to arrive at the presently claimed invention, a *prima facie* case of obviousness has not been established for claims 10, 21, or 33. Claims 11-20, 22-32, and 34-42 depend from independent claims 10, 21, or 33, and thereby incorporate the limitations thereof. As such, Applicant respectfully submits that claims 11-20, 22-32, and 34-42 are allowable over the combination of *Nies* and/or *Hashimoto* and *Goosen* and/or *Struszczyk* for at least the same reasons as discussed above with regard to claims 10, 21, or 33. Thus, the Applicant respectfully requests reconsideration and withdrawal of the rejections to claims 10-42 under 35 U.S.C. § 103(a) relative to the combination of *Nies* and/or *Hashimoto* and *Goosen* and/or *Struszczyk*.

### **SUMMARY**

In view of the foregoing, Applicant respectfully submits that the other rejections to the claims are now moot and do not, therefore, need to be addressed individually at this time. It will be appreciated, however, that this should not be construed as Applicant acquiescing to any of the purported teachings or assertions made in any action regarding the cited art or the pending application, including any Official Notice. Instead, Applicant reserves the right to challenge any of the purported teachings or assertions made in any action at any appropriate time in the future, should the need arise. Furthermore, to the extent that the Examiner has relied on any Official Notice, explicitly or implicitly, Applicant specifically requests that the Examiner provide references supporting the teachings officially noticed, as well as the required motivation, suggestion, or reason to combine the relied upon Notice with the other art of record.

Applicant believes claims 1-42 are in allowable form as discussed above. Thus, Applicant respectfully requests reconsideration of the application and allowance of the presently pending claims. In the event that the Examiner finds remaining impediment to a prompt allowance of this application that may be clarified through a telephone interview, the Examiner is requested to contact the undersigned attorney by telephone at (801) 533-9800.

Dated this 20th day of December, 2007.

Respectfully submitted,

/Fraser D. Roy, Reg.# 45666/

FRASER D. ROY  
Registration No. 45,666  
WORKMAN NYDEGGER  
Attorneys for Applicant  
Customer No. 057360

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